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| APPLICATION NO.                   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|------------------------|------------------|
| 10/537,103                        | 03/10/2006  | Ian Wilson           | PZ02101                | 1240             |
| 36335                             | 7590        | 04/16/2010           | EXAMINER               |                  |
| GE HEALTHCARE, INC.               |             |                      | PERREIRA, MELISSA JEAN |                  |
| IP DEPARTMENT 101 CARNEGIE CENTER |             |                      | ART UNIT               | PAPER NUMBER     |
| PRINCETON, NJ 08540-6231          |             |                      | 1618                   |                  |
|                                   |             |                      | MAIL DATE              | DELIVERY MODE    |
|                                   |             |                      | 04/16/2010             | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/537,103             | WILSON ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | MELISSA PERREIRA       | 1618                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 March 2010.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 5-32 is/are pending in the application.
- 4a) Of the above claim(s) 9-16,31 and 32 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,5-8 and 17-30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

Claims 1,5-32 are pending in the application. Claims 9-16,31 and 32 are withdrawn from consideration. Claims 2-4,33 and 34 were canceled in the amendment filed 3/8/10.

### ***Claims***

A claim being canceled must be indicated as “canceled;” ***the text of the claim must not be presented.*** Canceled and not entered claims must be listed by only the claim number and status identifier, without presenting the text of the claims.

### ***Response to Arguments***

1. Applicant's arguments filed 3/8/10 have been fully considered but they are not persuasive.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

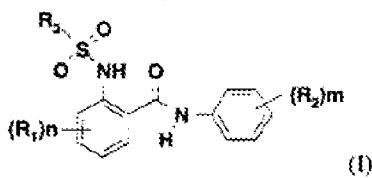
3. Claims 1,5-8 and 17-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (WO02/067761) in view of Weinstock et al. (WO00/78145A1) as stated in the office action mailed 12/7/09.

4. Applicant asserts that combining the teachings of Edwards et al. and Weinstock et al. could conceivably lead to a sulphonamidobenzamide compound linked to a metal

chelate, where the metal chelate comprises a metal that is suitable for in vivo imaging. There is no teaching, disclosing, or suggesting in Weinstock et al. about in vivo imaging, and consequently no teaching, disclosing, or suggesting about where to label the sulphonamidobenzamide compounds disclosed therein with an imaging moiety.

5. Edwards et al. teaches of the complexes  $M-C_h-L_n-(BM)_n$  wherein M is a radionuclide (i.e.  $^{99m}Tc$ ,  $^{111}In$ ,  $^{113m}In$ , etc.);  $C_h$  is a metal chelator (i.e. a  $N_4$  ligand,  $N_2S_2$  ligand);  $L_n$  is a linking group; and BM is a MSRA antagonist. The complexes are used for the diagnosis and monitoring of various cardiovascular diseases including but not limited to atherosclerosis, coronary artery disease, renal disease, thrombosis, transient ischemia, etc.

6. Weinstock et al. teaches of the MSRAs (below) used for treating cardiovascular disease including but not limited to atherosclerosis, coronary artery disease, renal disease, thrombosis, transient ischemia, etc.  $R_3$  may be  $R_1$ aryl, etc.;  $R_1$  and  $R_2$  may be hydrogen, alkyl, halo, etc.



7.

8. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute one macrophage scavenger receptor antagonist (MSRA), such as the sulphonamidobenzamides of Weinstock et al. for another analogous macrophage scavenger receptor antagonist (MSRA), such as that of Edwards et al. as both are used for treating cardiovascular diseases. Also, the simple substitution of one known,

equivalent element for another yields predictable results, such as binding macrophage scavenger receptors.

9. At the time of the invention it would have been obvious to one ordinarily skilled in the art to attach the imaging moiety of Edwards et al. to the sulphonamidobenzamides of Weinstock et al. at any reactive position along the sulphonamidobenzamide derivative, not excluding the locations corresponding to the substituents  $R^2, R^3, R^7, R^8, R^{12}$  of the instant claims as Edwards et al. teaches that a MSRA is attached to the metal chelator. There are a limited and finite number of attachment points on the aryl rings of the sulphonamidobenzamides of Weinstock et al. and therefore it is predictable to attach the imaging moiety at any of the reactive positions, including the aryl rings, on the sulphonamidobenzamides of Weinstock et al.

***New Grounds of Objection/Rejection Necessitated by the Amendment***

***Claim Objections***

10. Claim 1 is objected to because of the following informalities: the limitations  $R^1, R^{4-6}, R^{9-11}, R^{13}$  and  $R^{14}$  are not defined. Appropriate correction is required.

11. Claim 5 is objected to because of the following informalities: the instant claim 5 depends on a canceled claim 3.

***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1,5-8 and 17-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what substituents are acceptable for the limitations R<sup>1</sup>,R<sup>4-6</sup>,R<sup>9-11</sup>,R<sup>13</sup> and R<sup>14</sup>.

***Conclusion***

14. No claims are allowed at this time.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/  
Examiner, Art Unit 1618

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